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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/582,698

06/13/2006

Eli Ryssdal Andersen

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GE HEALTHCARE, INC.
IP DEPARTMENT
101 CARNEGIE CENTER
PRINCETON, NJ 08540-6231

EXAMINER

PERREIRA, MELISSA JEAN

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

10/01/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/582,698	Applicant(s) ANDERSEN ET AL.	
	Examiner MELISSA PERREIRA	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,6-11 and 13-15 is/are rejected.
- 7) ☒ Claim(s) 3-5,12 and 16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-16 are pending in the application. Claim 17 was cancelled in the amendment filed 5/28/08. Any objections and/or rejections from previous office actions that have not been reiterated in this office action are obviated.

Response to Arguments

1. Applicant's arguments with respect to claims 1-16 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1,2,6,10,11,13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Budsky et al. (CS272584B1).

4. Budsky et al. (CS272584B1) teaches of the preparation of the cyclic anhydride/bis anhydride of DTPA. Pyridine is added in the amount of 2.48 times that of DTPA and acetic anhydride is added in the amount of 2.64 times that of DTPA (p2, example 1). The reaction is carried out at 70°C at 8h without acetonitrile.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1,2,6-11 and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Budsky et al. (CS272584B1) in view of Dazzi (US 3,660,388) or Gibby (US 4,822,594).

7. Budsky et al. (CS272584B1) teaches of the preparation of the cyclic anhydride/bis anhydride of DTPA. Pyridine is added in the amount of 2.48 times that of DTPA and acetic anhydride is added in the amount of 2.64 times that of DTPA (p2, example 1). The reaction is carried out at 70°C at 8h without acetonitrile. Budsky et al. does not disclose the amounts of acetic anhydride to be more than 3,5 or 7 times that of DTPA.

8. Dazzi (US 3,660,388) discloses the process for the production of DTPA-bis(anhydride) by reacting DTPA with acetic acid (6 eq) and pyridine (6.5 eq) at 60°C for 48h (column 6, example 9) without the use of acetonitrile. The reaction of the tetracarboxylic acids of the disclosure is advantageously performed between room temperature and below the decomposition point of the tetracarboxylic acids (i.e. 10°C up to about 150°C), in excess of the monocarboxylic acid anhydride (i.e. acetic anhydride) and the presence of a tertiary nitrogen base (i.e. pyridine) (column 1, lines 45-55; column 2, lines 68+; column 3, lines 1-8).

Art Unit: 1618

9. Gibby (US 4,822,594) discloses the process for the production of DTPA-bis(anhydride) by reacting DTPA with a molar amount of acetic acid four times that of DTPA and a molar amount of pyridine that is six times the amount of DTPA at 65°C for 20h (column 4, example 1) without the use of acetonitrile. The reaction mixture can also be heated from 45°C to about 85°C (column 3, lines 52-61).

10. At the time of the invention it would have been obvious to one ordinarily skilled in the art to utilize acetic anhydride and pyridine for the process for the production of DTPA-bis(anhydride) without the use of acetonitrile as all of the disclosures are drawn to such a preparation. Dazzi discloses that pyridine is a particularly active base that accelerates the reaction and improves the yields while Budsky et al. minimizes the amount of pyridine in the reaction mixture. Pyridine is highly toxic and relatively expensive and therefore, it would be obvious to reduce the amount of pyridine to reduce toxicity. It would be obvious to one ordinarily skilled in the art to vary the reaction temperature and use varying amounts of acetic anhydride as all disclosures teach of the use a temperature range and of the use of excessive amounts of acetic anhydride in the preparation of DTPA-bis(anhydride).

11. Furthermore, it is obvious to vary and/or optimize the amount of (compound) provided in the composition, according to the guidance provided by (reference), to provide a composition having the desired properties such as the desired (ratios, concentrations, percentages, etc.). It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or

Art Unit: 1618

workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Conclusion

No claims are allowed at this time. Claims 3-5,12 and 16 are objected to for depending on a rejected claim.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA PERREIRA whose telephone number is (571)272-1354. The examiner can normally be reached on 9am-5pm M-F.

Art Unit: 1618

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/Melissa Perreira/
Examiner, Art Unit 1618